

REMARKS

This Amendment is submitted in reply to the final Office Action mailed on March 31, 2010. The Office Action provided a three-month shortened statutory period in which to respond, ending on June 31, 2010. Accordingly, this Amendment is timely submitted. Applicant does not believe there to be any fees due herewith this Amendment. The Commissioner is hereby authorized to charge any fees which may be required or credit any overpayment to Deposit Account No. 50-4498 in the name of Nestle Nutrition.

Claims 2, 3, 7, 8, 11-30 and 33-36 are currently pending. Claims 25-26 were previously withdrawn and Claims 1, 4-6, 8-10 and 31-32 were previously cancelled without prejudice or disclaimer. In the Office Action, Claims 2, 3, 7, 11-19, 24, 27, 28, 30 and 33-36 are rejected under 35 U.S.C. §103. In response, Claims 2, 7, 20 and 30 have been amended. These amendments do not add new matter. The amendments are supported in the specification at, for example, page 11, line 20-page 12, line 13; page 16, line 21-page 17, line 19; Figures 2 and 5. Applicant does not acquiesce in the correctness of the rejections or objections and reserves the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further, Applicant reserves the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

In the Office Action, Claims 2-3, 7, 11, 13, 17, 19, 24 27 and 28 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication No. 2004/0104246 to Kawaguchi, et al. ("*Kawaguchi*") in view of U.S. Patent No. 2,668,533 to Evans ("*Evans*") and further in view of U.S. Publication No. 2003/0226855 to Allanson et al. ("*Allanson*"). In view of the amendments and/or for the reasons set forth below, Applicant respectfully submits that the cited references are deficient with respect to the present claims.

Currently amended independent Claim 2 has been amended to recite, in part, a connector device comprising a cutting member for opening the laminated paper packaging system upon screwing the connector device onto the laminated paper packaging system, the cutting member protrudes from an interior of the first means and comprises a center axis that is offset from a center axis of the connector device. The amendments do not add new matter and are supported in the specification at, for example, page 11, line 20-page 12, line 13, Figure 2. Connector device can be manufactured by molding, such that all parts of the connector device may be

formed integrally therewith. In an embodiment, opening means includes a cutting member protruding from connector device on an interior of first means in a direction toward a laminated paper packaging system by pressing connector device thereto and/or by screwing connector device onto frame-like member, cutting member cuts laminated paper packaging system establishing a passageway for the fluid from the interior of laminated paper packaging system through connector device into feeding line of enteral administration set. See, specification, page 11, line 20-page 12, line 16. In contrast, Applicant respectfully submits that the cited references fail to disclose each and every element of the present claims.

For example, *Kawaguchi*, *Evans* and *Allanson* fail to disclose or suggest a connector device comprising a cutting member for opening the laminated paper packaging system upon screwing the connector device onto the laminated paper packaging system, the cutting member protrudes from an interior of the first means and comprises a center axis that is offset from a center axis of the connector device as required, in part, by the present claims. Instead, *Kawaguchi* discloses a beverage pack adapter having a pipe-shaped adapter body 12 whose distal end is inserted into an opening 21. The adapter body 12 comprises a pointed end 12a for puncturing a film 21a of a beverage pack. See, *Kawaguchi*, page 2, [0027]-[0029]. At no place in the disclosure does *Kawaguchi* disclose any structure that even resembles a first means that has first and second parts, let alone a cutting member integrally formed with first means that protrudes from an interior of the first means and comprises a center axis that is offset from a center axis of the connector device as required, in part, by the present claims.

Evans is entirely directed to a medical device for administration of medical liquids that is designed for complete sterilizing thereof and for economical manufacture. See, *Evans*, column 1, lines 1-23. At no place in the disclosure does *Evans* disclose any structure that even resembles a first means that has first and second parts, let alone a cutting member integrally formed with first means that protrudes from an interior of the first means and comprises a center axis that is offset from a center axis of the connector device as required, in part, by the present claims. Indeed, the Patent Office cites *Evans* simply for the disclosure of venting means. See, Office Action, pages 6-7.

Allanson is entirely directed to a tube 10, a hinge plate 20, an elastomeric seal 70 and a clamp ring 60, which are all separately manufactured parts. See, *Allanson*, page 4, [0040]:

Figures 1 and 10. At no place in the disclosure does *Allanson* disclose any structure that even resembles a first means that has first and second parts, let alone a cutting member integrally formed with first means that protrudes from an interior of the first means and comprises a center axis that is offset from a center axis of the connector device as required, in part, by the present claims.

Accordingly, Applicant respectfully submits that the cited references fail to disclose or suggest each and every element of independent Claim 2.

Currently amended independent Claim 7 has been amended to recite, in part, a tubular first spike for penetrating the first surface of the laminated paper packaging system and defining a second part of the passageway, the first spike defining a point, a first rim for fixedly attaching the connector device to the first surface of the laminated paper packaging system upon penetration of the first spike and pressing of the connector device against the first surface of the laminated paper packaging system, the first rim located at a fixed first distance from the point of the first spike, and a second rim for fixedly attaching the connector device to an interior surface within said laminated paper packaging system, the second rim formed of a flexible material and integrally with the connector device, the second rim located at a fixed second distance from the point of the spike, the second distance being less than the first distance. The amendments do not add new matter and are supported in the specification at, for example, page 16, line 21-page 17, line 19; Figure 5.

As discussed in the specification, a connector device 1 shown on the left hand side in Figure 5 comprises section 5, i.e. tube portion, for attachment of the feeding line of the enteral administration set. Two rims 50,51 are provided. Rims 50, 51 may extend in parallel around spike 20 and may be axially spaced from each other at a predetermined distance. This predetermined distance may be chosen such that laminated paper packaging system 4 and aluminum foil 17 are fittingly arranged between rim 50 and rim 51. Rim 51, which is arranged nearer to the point of spike 20, is made from a flexible material whereas rim 50 is made from a rigid material. The flexibility of rim 51 is important in this embodiment because rim 51 must be introduced through hole 21 (see Figure 4) into the interior of the laminated paper packaging system without damaging the laminated paper packaging system. In order to allow such introduction, rim 51 must be sufficiently flexible. Once spike 20 has been introduced into the

interior of laminated paper packaging system 4 laminated paper packaging system 4 and aluminum foil 17 are fittingly compressed between rim 51 and rim 50 thus establishing a tight fit. Composition may then exit from the interior of laminated paper packaging system 4 through the established passageway 5a. See, specification, page 16, line 21-page 17, line 19.

Further, the specification also states that connector device can be manufactured by molding, an in particular flexible rim can be manufactured by co-molding it together with the remainder of connector device in a single step. In an embodiment, the whole connector device may be molded from a rigid material and, in another embodiment, the first rim and second rim may be made of different material but co-molded together. See, specification, page 17, lines 4-19. Such a configuration provides a connector device with improved strength and integrity.

The Patent Office asserts that the skilled artisan would be motivated to modify *Allanson* to have integrally formed first and second rim means and states that an "integrally formed assembly of clamp ring 50 and tube 10 allows the connector device of *Allanson* to be manufactured as a single piece, while eliminating the step for a user to thread clamp ring 50 to tube 10." See, Office Action, page 9, lines 5-7. However, Applicant disagrees and submits that the structure of *Allanson* would not provide for integral first and second rim means that are spaced apart at a fixed distance. Indeed, the skilled artisan would not be motivated to modify *Allanson* to arrive at the present claims because *Allanson* is directed to an entirely different device with an entirely different mode of operation.

For example, in every embodiment of *Allanson*, the seal 30, 70, hinge plate 20, etc. are all configured to elastically deform to either expand to traverse over a lock ring stop 14 or elastically deform to reside in a reduced diameter section 15. Indeed, *Allanson* explicitly states that, for example, "[b]ecause seal 30 is formed of a flexible thermoplastic elastomer material, it may be easily slid along elongate tube 10 and elastically deformed as it is pulled over lock ring stop 14." See, *Allanson*, page 2, paragraph 26. *Allanson* further states that "[d]uring installation, lock ring 40 is slid along elongate tube 10 and is forced over lock ring stop 14. Lock ring 40 may be formed with sufficient resiliency that it may be temporarily deformed as it passes over lock ring stop 14. However, once lock ring 40 is pulled over lock ring stop 14, it returns to its original shape so as to lie flush against the outer wall of elongate tube 10." See, *Allanson*, page 2, paragraph 27. As such, it is clear that each and every embodiment of *Allanson* requires a seal

30, 70, hinge plate 20, etc. to traverse the elongate tube 10 to arrive at a final location along the elongate tube 10. This mode requires moveable pieces that would not function properly with the connector device of the present claims.

Further, Applicant respectfully submits that the cited references fail to disclose each and every element of the present claims. For example, *Kawaguchi*, *Evans* and *Allanson* fail to disclose or suggest a tubular first spike for penetrating the first surface of the laminated paper packaging system and defining a second part of the passageway, the first spike defining a point, a first rim for fixedly attaching the connector device to the first surface of the laminated paper packaging system upon penetration of the first spike and pressing of the connector device against the first surface of the laminated paper packaging system, the first rim located at a fixed first distance from the point of the first spike, and a second rim for fixedly attaching the connector device to an interior surface within said laminated paper packaging system, the second rim formed of a flexible material and integrally with the connector device, the second rim located at a fixed second distance from the point of the spike, the second distance being less than the first distance as is required, in part, by independent Claim 7.

Instead, *Kawaguchi* discloses an elongated pipe adapter body 12 that can be fixed to a beverage pack through a hole on the beverage pack. The elongated pipe adapter body 12 has a passage 12g for fluid to pass through. See *Kawaguchi*, Figures 1-2. The elongated pipe adapter body 12 is designed so that the top joint 12 of the body 12 can be fitted within a tube 30. The elongated pipe adapter body 12 also has a bottom pointed end 12 that fits entirely within a fixing member 14 and the beverage pack. As a result, most of the entire elongated pipe adapter body 12 is within positioned within the tube 30 and the fixing member 14 and the beverage pack during operation. At no place in the disclosure does *Kawaguchi* disclose or suggest a first rigid rim and a second flexible rim formed integrally with the connector device and at fixed distances from each other.

Evans discloses an outlet member 18 having parallel passages 36 and 38 for fluid flow and for venting, respectively. See *Evans*, Figures 1-2. The outlet member 18 is designed so that the entire cylindrical tip portion 20 fits into a hole of a bottle 10. Meanwhile, the outlet member 18 has a bottom portion 34 that has a passage 40 to receive a tip of a bottle 24 while the other parallel passage 38 is vented open to the air (via the check valve ball 56 and the filter medium

58). At no place in the disclosure does *Evans* disclose or suggest a first rigid rim and a second flexible rim formed integrally with the connector device and at fixed distances from each other.

Allanson discloses a tube 10, a hinge plate 20, an elastomeric seal 70 (cited by the Patent Office as a flexible rim) and a clamp ring 60 (cited by the Patent Office as a rigid rim), which are all separately manufactured parts. See, *Allanson*, page 4, [0040]; Figures 1 and 10. Indeed, *Allanson* even discloses that “seal 70 may be slid along the body of tube 10” and that “[c]lamp ring 60 is [] threaded onto elongate tube 10.” See, *Allanson*, page 4, [0038], [0040]. This is in direct contrast to the present claims that require the rigid tube to have formed integrally therewith first and second rim means, which are located at fixed distances with respect to each other. At no place in the disclosure does *Allanson* disclose or suggest a first rigid rim and a second flexible rim formed integrally with the connector device and at fixed distances from each other. For at least the above-mentioned reasons, Applicant respectfully submits that the cited references fail to disclose or suggest each and every element of the present claims.

Applicant respectfully submits that it is only with a hindsight reconstruction of Applicant's claimed invention that the Patent Office is able to even attempt to piece together the teachings of the prior art so that the claimed invention is allegedly rendered obvious. However, the claims must be viewed as a whole as defined by the claimed invention and not dissected into discrete elements to be analyzed in isolation. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983); *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995). One should not use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 837 F.2d at 1075. (Fed. Cir. 1988).

In sum, the cited references fail to even recognize the advantages, benefits and/or properties of the connector devices in accordance with the present claims. For at least the reasons discussed above, Applicant respectfully submits that Claims 2-3, 7, 11, 13, 17, 19, 24 27 and 28 are novel, nonobvious and distinguishable from the cited references.

Accordingly, Applicant respectfully requests that the rejections of Claims 2-3, 7, 11, 13, 17, 19, 24 27 and 28 under 35 U.S.C. §103 be reconsidered and withdrawn.

In the Office Action, Claim 12 is rejected under 35 U.S.C. §103(a) as being unpatentable over *Kawaguchi* in view of *Evans*, in view of *Allanson* and further in view of U.S. Patent No.

4,921,139 to Quinn et al. ("*Quinn*"). Claims 14, 16 and 18 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Kawaguchi* in view of *Evans* and *Allanson* and further in view of U.S. Patent No. 5,993,422 to Schafer ("*Schafer*"). Claim 15 is rejected under 35 U.S.C. §103(a) as being unpatentable over *Kawaguchi*, in view of *Evans* and *Allanson* and further in view of U.S. Patent No. 2,969,063 to Broman ("*Broman*"). Applicant respectfully submits that the patentability of Claims 2 and 7 as previously discussed renders moot the obviousness rejections of Claims 12, 14-16 and 18 that depend therefrom. In this regard, the cited art fails to teach or suggest the elements of Claims 12, 14-16 and 18 in combination with the novel elements of Claims 2 and 7.

In the Office Action, Claims 20-23 and 29 are rejected under 35 U.S.C. §103 as being unpatentable over *Kawaguchi* in view of U.S. Patent No. 4,801,007 to Rule ("*Rule*") in further view of U.S. Patent No. 5,141,133 to Ninomiya ("*Ninomiya*"). In view of the amendments and/or for the reasons set forth below, Applicant respectfully submits that the cited references are deficient with respect to the present claims.

Currently amended independent Claim 20 recites, in part, a connector device comprising a cutting member rotatable with the connector device upon screwing the connector device onto the frame-like member of the packaging system, the cutting member projecting toward the surface such that the cutting member first cuts the surface only after engagement of the first means of the connector device with the first threaded portion of the packaging system, the cutting member is integrally formed with first means, protrudes from an interior of the first means and comprises a center axis that is offset from a center axis of the connector device. The amendment does not add new matter and is supported in the specification at, for example, page 11, line 21-page 12, line 16. As discussed above, connector device can be manufactured by molding, such that all parts of the connector device may be formed integrally therewith. In an embodiment, opening means includes a cutting member protruding from connector device on an interior of first means in a direction toward a laminated paper packaging system by pressing connector device thereto and/or by screwing connector device onto frame-like member, cutting member cuts laminated paper packaging system establishing a passageway for the fluid from the interior of laminated paper packaging system through connector device into feeding line of enteral administration set. See, specification, page 11, line 21-page 12, line 16. In contrast,

Applicant respectfully submits that the cited references are deficient with respect to the present claims.

For example, *Kawaguchi*, *Rule* and *Ninomiya* all fail to disclose or suggest a connector device comprising a cutting member rotatable with the connector device upon screwing the connector device onto the frame-like member of the packaging system, the cutting member projecting toward the surface such that the cutting member first cuts the surface only after engagement of the first means of the connector device with the first threaded portion of the packaging system, wherein the cutting member is integrally formed with first means, protrudes from an interior of the first means and comprises a center axis that is offset from a center axis of the connector device as required, in part, by the present claims. Instead, *Kawaguchi* discloses a beverage pack adapter having a pipe-shaped adapter body 12 whose distal end is inserted into an opening 21. The adapter body 12 comprises a pointed end 12a for puncturing a film 21a of a beverage pack. See, *Kawaguchi*, page 2, [0027]-[0029]. At no place in the disclosure does *Kawaguchi* disclose any structure that even resembles a first means that has first and second parts, let alone a cutting member integrally formed with first means, protruding from an interior of first means, and comprising a center axis that is offset from a center axis of the connector device.

Rule discloses a tubular teat mounting 21 having a passage. The tubular teat mounting 21 has a top portion that is entirely covered by a teat. See *Rule*, Figures 4-7. The tubular teat mounting 21 also has a bottom spike 34 that is designed to fit entirely within a container 11. At no place in the disclosure does *Rule* disclose any structure that even resembles a first means that has first and second parts, let alone a cutting member integrally formed with first means, protruding from an interior of first means, and comprising a center axis that is offset from a center axis of the connector device.

Ninomiya discloses a pouring plug having a tubular body 1 and a lid 2 that fits within the tubular body 1. The lid 2 includes a bottom edge portion having a saw tooth blade 12a. The pouring plug is designed to fit on top of the container with only the saw tooth blade 12a rupturing a surface of the container. See *Ninomiya*, Figure 4. As a result, most of the tubular body 1 and a lid 2 does not enter the container. Further, at no place in the disclosure does *Ninomiya* disclose any structure that even resembles a first means that has first and second parts.

let alone a cutting member integrally formed with first means, protruding from an interior of first means, and comprising a center axis that is offset from a center axis of the connector device. Accordingly, *Kawaguchi*, *Rule* and *Ninomiya* all fail to disclose or suggest each and every element of the present claims.

In addition, Applicant further submits that the skilled artisan would have no reason to combine *Ninomiya* with *Kawaguchi* and *Rule* to arrive at independent Claim 20 because the cited references are entirely directed to devices having different modes of operation. As previously discussed, *Kawaguchi* discloses an elongated pipe adapter body 12 where most of the entire elongated pipe adapter body 12 is within positioned within the tube 30 and the fixing member 14 and the beverage pack during operation. Similarly, *Rule* discloses a tubular teat mounting 21 having a passage having a top portion that is entirely covered by a teat and a bottom spike 34 that is designed to fit entirely within a container 11.

In contrast, *Ninomiya* discloses a pouring plug having a tubular body 1 and a lid 2 that fits within the tubular body 1. The lid 2 includes a bottom edge portion having a saw tooth blade 12a. The pouring plug is designed to fit on top of the container with only the saw tooth blade 12a rupturing a surface of the container. See *Ninomiya*, Figure 4. As a result, most of the tubular body 1 and a lid 2 does not enter the container.

On the other hand, *Kawaguchi* and *Rule* disclose devices where the entire bottom portions of the devices are designed to enter and fit within the container and container walls. For example, the elongated pipe adapter body of *Kawaguchi* includes the bottom pointed end that fits within the container to form a tight fluid flow with the container wall. See *Kawaguchi*, Figure 4. The tubular teat mounting of *Rule* has the bottom spike that is designed to fit and be locked entirely within the container. In view of the teachings of *Kawaguchi* and *Rule*, Applicant respectfully submits that the skilled artisan would not shorten the bottom pointed end of the elongated pipe adapter body in *Kawaguchi* or the bottom spike of the tubular teat mounting of *Rule* in view of *Ninomiya* because to do so would render the devices of *Kawaguchi* and *Rule* inoperable.

Applicant respectfully submits that it is only with a hindsight reconstruction of Applicant's claimed invention that the Patent Office is able to even attempt to piece together the teachings of the prior art so that the claimed invention is allegedly rendered obvious. However,

the claims must be viewed as a whole as defined by the claimed invention and not dissected into discrete elements to be analyzed in isolation. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983); *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995). One should not use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 837 F.2d at 1075. (Fed. Cir. 1988).

For at least the above-mentioned reasons, Applicant respectfully submits that Claims 20-23 and 29 are novel, nonobvious and patentable in view of the cited references.

Accordingly, Applicant respectfully submits that the rejection of Claims 20-23 and 29 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

In the Office Action, Claims 30 and 33-36 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Allanson*. In view of the amendments and/or for the reasons set forth below, Applicant respectfully submits that the cited reference is deficient with respect to the present claims.

Currently amended independent Claim 30 recites, in part, a connector device comprising a rigid tube part, the rigid tube part having formed integrally therewith at about said second end a first rim means comprising a rigid material and a second rim means comprising a flexible material more distal thereon, the first rim means being located at a fixed distance from the second rim means. The amendment does not add new matter and is supported in the specification at, for example, page 16, line 21-page 17, line 19; Figure 5. As discussed in the specification, connector device can be manufactured by molding, an in particular flexible rim can be manufactured by co-molding it together with the remainder of connector device in a single step. In an embodiment, the whole connector device may be molded from a rigid material and, in another embodiment, the first rim and second rim may be made of different material but co-molded together. See, specification, page 16, line 21-page 17, line 19. Such a configuration provides a connector device with improved strength and integrity. In contrast, Applicant respectfully submits that *Allanson* is deficient with respect to the present claims.

As discussed above, *Allanson* is directed to an entirely different device with an entirely different mode of operation. For example, in every embodiment of *Allanson*, the seal 30, 70, hinge plate 20, etc. are all configured to elastically deform to either expand to traverse over a

lock ring stop 14 or elastically deform to reside in a reduced diameter section 15. Indeed, *Allanson* explicitly states that, for example, “[b]ecause seal 30 is formed of a flexible thermoplastic elastomer material, it may be easily slid along elongate tube 10 and elastically deformed as it is pulled over lock ring stop 14.” See, *Allanson*, page 2, paragraph 26. *Allanson* further states that . “[d]uring installation, lock ring 40 is slid along elongate tube 10 and is forced over lock ring stop 14. Lock ring 40 may be formed with sufficient resiliency that it may be temporarily deformed as it passes over lock ring stop 14. However, once lock ring 40 is pulled over lock ring stop 14, it returns to its original shape so as to lie flush against the outer wall of elongate tube 10.” See, *Allanson*, page 2, paragraph 27. As such, it is clear that each and every embodiment of *Allanson* requires a seal 30, 70, hinge plate 20, etc. to traverse a tube 10 to arrive at a final location along the elongate tube 10. This mode requires moveable pieces that would not function properly with the connector device of the present claims.

Further, *Allanson* fails to disclose or suggest a connector device comprising a rigid tube part, the rigid tube part having formed integrally therewith at about said second end a first rim means comprising a rigid material and a second rim means comprising a flexible material more distal thereon, the first rim means being located at a fixed distance from the second rim means as is required, in part, by independent Claim 30. Instead, *Allanson* discloses a tube 10, a hinge plate 20, an elastomeric seal 70 (cited by the Patent Office as a flexible rim) and a clamp ring 60 (cited by the Patent Office as a rigid rim), which are all separately manufactured parts. See, *Allanson*, page 4, [0040]; Figures 1 and 10. Indeed, *Allanson* even discloses that “seal 70 may be slid along the body of tube 10” and that “[c]lamp ring 60 is [] threaded onto elongate tube 10.” See, *Allanson*, page 4, [0038], [0040]. This is in direct contrast to the present claims that require the rigid tube to have formed integrally therewith first and second rim means, the first rim means being located at a fixed distance from the second rim means.

For at least the reasons discussed above, Applicant respectfully submits that Claims 30 and 33-36 are novel, nonobvious and distinguishable from the cited reference and are in condition for allowance.

Therefore, Applicant respectfully requests that the rejections of Claims 30 and 33-36 under 35 U.S.C. §103 as unpatentable over *Allanson* be reconsidered and withdrawn.

For the foregoing reasons, Applicant respectfully requests reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

Nestlé HealthCare Nutrition
12 Vreeland Road, 2nd Floor
Florham Park, NJ 07932
(973) 593-7553

By: _____/gm//
Gary M. Lobel
Attorney for Applicant
Reg. No. 51,155

Dated: May 6, 2010